

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,758	10/05/2001	Monica Montano	27708/04004	4322
24024	7590	12/31/2002	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			UNGAR, SUSAN NMN	
		ART UNIT	PAPER NUMBER	
		1642	DATE MAILED: 12/31/2002	

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/972,758	Applicant(s) Montano et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Apr 9, 2002
 - 2a) This action is FINAL. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-26 is/are pending in the application.
 - 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) _____ is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claims 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved; corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: Notice to Comply

Art Unit: 1642

1. Claims 1-26 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.8821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. In particular, claim 14 is drawn to SEQ ID NO:3, however, neither the paper copy of the sequence listing nor the Raw Sequence Listing prepared by STIC have three sequences.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821 (g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH

statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1-6, 25, 26 are drawn to a polynucleotide classified in Class 536, subclass 23.1.

Group 2. Claims 7-13 are drawn to a polypeptide, SEQ ID NO:2 and functional equivalents thereof, classified in class 530, subclass 300+.

Group 3. Claim 14 is drawn to a polypeptide, SEQ ID NO:3, classified in Class 530, subclass 350.

Group 4. Claims 15-16 are drawn to an antibody, classified in Class 530, subclass 387.1.

Groups 5-11. Claims 17-18 are drawn to a cancer detection method comprising detecting seven different types of cancers, each of which is a distinct invention classified in Class 435, subclass 7.1. Applicant is required to elect a single invention.

Group 12-18. Claims 19-21 are drawn to a cancer detection method comprising detecting seven different types of cancers, each of which is a distinct invention classified in Class 435, subclass 6. Applicant is required to elect a single invention.

Group 19-25. Claims 22-23 are drawn to a method of decreasing proliferation of cancer cells, *in vivo* in seven different types of cancer comprising contacting the cells with EDG1 protein or a functional equivalent thereof, each of which is

Art Unit: 1642

a distinct invention, classified in Class 514, subclass 2. Applicant is required to elect a single invention.

Group 26-32. Claims 22-23 are drawn to a method of decreasing proliferation of cancer cells in seven different cancer cell types, *in vitro* comprising contacting the cells with EDG1 protein or a functional equivalent thereof each of which is a distinct invention, classified in Class 435, subclass 4. Class 514, subclass 2. Applicant is required to elect a single invention.

Group 33-39. Claims 22 and 24 are drawn to a method of decreasing proliferation of cancer cells in seven different cancer types, *in vivo* via gene therapy each of which is a distinct invention, classified in Class 514, subclass 44. Class 514, subclass 2. Applicant is required to elect a single invention.

Group 40-46. Claims 22 and 24 are drawn to a method of decreasing proliferation of cancer cells in seven different cancer cell types, *in vitro* via transfection each of which is a distinct invention; classified in Class 435, subclass 6. Applicant is required to elect a single invention.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 5-46 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Art Unit: 1642

The inventions of Groups 2/4 and 5-11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP § 806.05(h)*]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography and the polypeptide product can be used in a materially different process such as an antigenic source for the production of antibodies.

The inventions of Groups 1 and 12-18, 33-46 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP § 806.05(h)*]. In the instant case the polynucleotide product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 2 and 19-32 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP § 806.05(h)*]. In the instant case the polypeptide product can be used in a materially different process such as affinity chromatography.

Art Unit: 1642

The inventions of 1 and 5-11, 19-32 are not at all related because the polynucleotide of invention 1 is not used in any of the methods of claims 5-11, 19-32.

The inventions of groups 2-3 and 12-18 and 22-46 are not at all related because the polypeptides of inventions 2-3 are not used in any of the methods of Groups 12-18 and 22-46.

The inventions of groups 4 and 12-46 are not at all related because the antibody of Group 4 is not used in any of the methods of Groups 12-46.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

Art Unit: 1642

to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
December 23, 2002

